UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
WACO DIVISION

NATERA, INC.,	)	
Plaintiff,	)	Case No. 6:21-cv-540
v.	)	
GUARDANT HEALTH, INC.,	)	
Defendant.	)	

COMPLAINT

Plaintiff Natera, Inc. ("Natera"), by and through its counsel, hereby files this Complaint against Defendant Guardant Health, Inc. ("Guardant"), and alleges as follows:

SUMMARY OF THE ACTION

1. Natera is a leader in non-invasive genetic testing. In August of 2017, Natera launched Signatera(™), a novel personalized approach to cancer detection in plasma. The technology analyzes whole-exome sequencing data from a patient's tumor sample in order to custom design individual-specific assays, targeting mutations known to be present in the patient's tumor tissue ("tumor signatures"). This uniquely personalized "tumor informed" approach enables physicians to accurately detect and monitor cell-free tumor DNA ("ctDNA"). The Signatera test has been shown to detect the presence of ctDNA earlier than traditional tools, and with fewer false positives.

2. Detecting and monitoring ctDNA in the blood of a cancer patient allows physicians to detect minimal/molecular residual disease ("MRD") and recurrence of a patient's cancer. Detection of residual disease can lead to better patient outcomes by informing clinical decisions,

including whether to treat with chemotherapy after surgery, whether to biopsy a suspicious lesion, or whether to continue or discontinue a particular treatment strategy.

3. This case arises from Guardant's campaign of false and misleading commercial statements regarding the performance of its purportedly-competitive MRD product, "Reveal."[1]

4. Reveal is a "tumor-naive test," which means that it looks for evidence of alterations in the same genomic regions for every patient, without accounting for the mutational signature of the specific patient's particular tumor.

5. Guardant supported and co-authored a study (the "Study") that it grossly mischaracterized and misrepresented in order to enhance the performance claims for its test. *See* Ex. A. Guardant then disseminated these false and misleading claims regarding the effectiveness of its test to influence healthcare professionals and patients to choose it over other MRD testing products, such as Natera's product, Signatera. Such misinformation regarding the efficacy of the test not only put competitors such as Natera at a competitive disadvantage but also endangered the health and safety of patients who rely on MRD testing for important clinical decisions.

6. The Study is so narrow and the data so limited that it cannot possibly support Guardant's broad performance claims.

7. Even prior to the publication of the Study, Guardant began spreading false and misleading information, allegedly based on the Study, to drive market share away from competitors such as Natera. Guardant's false and misleading statements about the performance of its MRD test have caused and—unless enjoined—will continue to cause significant injury to Natera, and potentially to cancer patients.

[1] Guardant has previously referred to this test as its "Lunar-1" test.

8. Guardant's actions violate Section 43(a) of the Lanham Act and amount to unfair competition. Natera seeks monetary and injunctive relief based on Guardant's unlawful conduct.

PARTIES

9. Plaintiff Natera is a corporation organized and existing under the laws of the State of Delaware and has its principal place of business 13011 McCallen Pass, Building A Suite 100, Austin, Texas 78753. Natera is a global leader in cell-free DNA testing. Natera's mission is to improve disease management around the globe, with a focus on women's health, oncology, and organ health.

10. Defendant Guardant is a corporation organized and existing under the laws of the State of Delaware and has its principal place of business at 505 Penobscot Dr., Redwood City, California 94063. Guardant may be served with process via its registered agent, CT Corporation System, 818 West Seventh Street, Suite 930, Los Angeles, California 90017.

JURISDICTION AND VENUE

11. This is an action for false advertising and unfair competition under Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and for common law unfair competition.

12. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338. This Court has supplemental jurisdiction over Natera's state law claim pursuant to 28 U.S.C. § 1367.

13. This Court has personal jurisdiction over Guardant because, among other things, Guardant has purposefully availed itself of the privileges and benefits of the laws of the State of Texas, and Guardant conducts business in this District. And, as more fully described herein, Guardant disseminated false and misleading advertisements to physicians, patients, healthcare professionals, and others residing in Texas.

14. Venue is proper in this District pursuant to 28 U.S.C. § 1391 because Guardant transacts business in this District, and a substantial part of the events giving rise to Natera's claims occurred and are continuing to occur in this District. Additionally, Guardant's actions injured Natera in this District, where Natera is headquartered.

FACTUAL ALLEGATIONS

A. *Natera Launches Signatera.*

15. On August 21, 2017, Natera launched Signatera, a bespoke circulating tumor DNA ("ctDNA") test designed to detect and measure MRD in patients previously diagnosed with cancer, to aid detection of cancer recurrence. Signatera is able to detect MRD earlier than traditional methods, and thereby helps optimize treatment decisions. The test is available for both clinical and research use and has been granted three Breakthrough Device Designations by the FDA for multiple cancer types and indications. Signatera's performance has been clinically validated in multiple cancer types including colorectal, non-small cell lung, breast, and bladder cancers.

B. *Guardant Launches Reveal, a Tumor-Naïve MRD Test.*

16. On or around February 16, 2021, Guardant released a "tumor-naïve" MRD test, called Reveal. Like Signatera, Reveal is a ctDNA test, designed to detect the presence of MRD in patients who have been previously diagnosed with cancer. Reveal is only validated for use in colorectal cancer, and has not been granted FDA Breakthrough Device Designation.

17. Guardant supported and co-authored the Study on the performance characteristics of Reveal, which was published on April 29, 2021. As explained in greater detail below, the Study's limited data and narrow focus cannot support Guardant's broad, inaccurate, and misleading performance claims. Although Guardant's marketing relies on the Study, the design of

the Study and the data generated make these performance claims unsupported, unwarranted, and worse, unreliable.

C. *Measuring Performance of a ctDNA Test.*

18. Researchers generally evaluate the performance of a ctDNA test like Signatera or Reveal using two key metrics: sensitivity and specificity. Additional metrics relevant to the assessment of MRD performance are positive predictive value ("PPV"), negative predictive value ("NPV"), diagnostic lead time (the time between first MRD detection and confirmed radiographic recurrence), outcomes analysis, and hazard ratios ("HR").

19. Sensitivity measures the percentage of positive results that are correctly identified. A test with high sensitivity is more likely to correctly identify the presence of cancer in a blood sample in which MRD is in fact present, as verified by a clinical "gold standard," including that the patient subsequently experienced clinical or radiographic recurrence.

20. Specificity measures the percentage of negative results that are correctly identified. A test with high specificity is more likely to correctly identify the absence of cancer in a blood sample when no MRD is in fact present, as verified by a clinical "gold standard," including that the patient remains relapse-free or progression-free.

21. In order to be accurate and meaningful, sensitivity and specificity must be calculated and reported together in the same analysis of the same set of samples. Sensitivity and specificity cannot be interpreted by themselves, because those values can differ from analysis to analysis, based on several factors, including differences in patient cohort.

22. As explained in greater detail below, Guardant's marketing claims fundamentally misrepresent the data and conclusions of the Study to either obfuscate or artificially boost the above metrics and other performance data for the test.

D. *The Study Cannot Support Guardant's Marketing Claims.*

23. The Study's data and analysis fail to support its marketing claims in four primary ways: (1) the Study reported two different metrics for serial test performance: "longitudinal" and "surveillance," the latter metric having no legitimate clinical basis or scientific significance; (2) the Study does not include key metrics in its "surveillance" analysis, rendering Guardant's marketing claims into misleading half-truths; (3) the data was generated in a population that is not representative of Guardant's intended use for its test, such that Guardant's marketing claims reflect artificially elevated or unsupported metrics; and (4) Guardant's performance claims exclude data from the Study, which, if included, would substantially detract from those claims.

i. Guardant's Use of "Surveillance" Analysis Makes Guardant's Sensitivity Claims Misleading.

24. The Study reported two different metrics for serial test performance: "longitudinal" and "surveillance" metrics. These metrics refer to different points in time at which the researchers collect blood samples from patients following the initial (landmark) blood draw. Longitudinal analysis is typically limited to patients with *any* subsequent blood draw after the initial timepoint; no matter how much time has passed following the initial blood draw. Researchers frequently use longitudinal analyses because they offer significant real-world clinical value, similar to other blood-based biomarkers such as CEA (Carcinoembryonic Antigen).

25. Under a longitudinal analysis, the Study reported a sensitivity score of 69% and specificity score of 100%.[2]

[2] This 100% specificity score, facially indicating a false positive rate of zero, was only possible with the exclusion of two patients from the sample set, as explained in Paragraph 38, below. This analysis was initially presented in 2020, providing ample time for an update with additional follow-up.

26. In addition to reporting the sensitivity score determined by the longitudinal analysis, the Study engaged in what it called a "surveillance" analysis, which, unlike longitudinal analysis, is not supported by medical or academic literature. Only under this unusual and unsupported analysis did the Study report a favorable sensitivity score. The Study defined a "surveillance" draw as a blood sample obtained within four months of clinical recurrence. The Study offered no scientific explanation or support for its arbitrary four-month cut-off date, except for a false attribution of this methodology to a study by Reinert et al, which in fact employed no such cutoff. Under the "surveillance" analysis, the authors reported a sensitivity metric of 91%, but no specificity metric.

27. Guardant's marketing claims of 91% in the "surveillance" context are derived from the particular and peculiar definition of "surveillance" in the Study, but Guardant intends for physicians and patients to confuse the Study definition with the commonly understood plain meaning of the term surveillance, i.e., time points or time periods after completion of definitive treatments.

28. Guardant's marketing claims, including claims made in investor presentations, deliberately confound the Study's peculiar definition of "surveillance" with "monitoring." In one investor presentation to Bank of America, Guardant's CEO describes surveillance as "multiple shots on goal," but this is *contrary* and in stark contrast to the definition of "surveillance" used in the Study—a single "shot on goal" within a four-month time period of recurrence.

ii. Guardant's Reliance on "Surveillance" Analysis Misleadingly Masks the Absence of Specificity Data.

29. Importantly, the Study did not report the corresponding specificity metric for the surveillance analysis. It is extremely unusual and misleading for a laboratory like Guardant to make marketing claims about their test using a sensitivity metric without presenting the

corresponding specificity metric, as doing so makes it impossible to draw any meaningful conclusions about a test's performance in that setting. Most scientists would consider a test invalid if both sensitivity and specificity cannot be evaluated together.

30. Presenting sensitivity without the corresponding specificity is contrary to guidance from the Food & Drug Administration ("FDA"), Clinical Laboratory Improvement Amendments ("CLIA"), and the New York State Department of Health ("NYSDOH").

31. A test with a high sensitivity metric could have a low specificity rate; if a laboratory issued a positive test report for every patient without performing any testing at all, it would have a 100% sensitivity score. However, that test would have a very low specificity score, because it would have missed every true negative patient. The real-world consequences of such a defective test—individual patients being misinformed that they have tested positive for MRD—cannot be overstated. Such false positives may cause a patient to undergo unnecessary biopsies, surgeries, chemotherapy, radiation treatment, or other invasive and damaging procedures; result in emotional trauma to the patient and her loved ones; and needlessly waste time and other resources on expensive medical care.

32. Indeed, a specificity score could not be meaningfully determined by utilizing the Study's unusual and unsupported "surveillance" method, because by definition, all patients in the sample group had experienced a recurrence of cancer, and it would be impossible to obtain a false positive within such a group.

33. Because the authors did not determine or report the specificity measure for the surveillance analysis, the Study fails to rule out the possibility that the test generates excessive false-positives. The intentional omission of this key metric is highly suspicious and deeply troubling. Because of Guardant's false and misleading marketing, patients and physicians are

under the false impression that the test has a high specificity in the surveillance setting, when in fact they have no way of knowing. Such misinformation disseminated to the oncology community risks serious adverse outcomes for patients.

34. The Study cannot support Guardant's marketing claims, because the Study analyzed "longitudinal" and "surveillance" samples only in patients who experienced recurrence, rather than a representative sample of patients. In other words, the Study only suggests how well the test could detect the *presence* of cancer, without claiming to determine how well the test was able to detect the *absence* of cancer. This makes it impossible to calculate specificity and renders Guardant's specificity claims in its marketing unsupported, if not irresponsible.

35. The Study evaluated "longitudinal" and "surveillance" draws only in patients who had experienced recurrence, so it has limited clinical value given the critical need for physicians and patients to know whether patients have cancer *or not*. The Study's limited scope (i.e., its exclusive limitation to patients who had experienced recurrence) has been exploited and abused by Guardant's marketing materials. Guardant's marketing materials present an artificially high sensitivity score of 91% without reporting a corresponding specificity score in its "surveillance analysis"

36. In the Discussion section of the Study, the authors state, "the lack of systematic longitudinal and surveillance draws across all patients precluded a comprehensive assessment."

37. Guardant's marketing materials pair its unsupported 91% sensitivity score with a 100% specificity claim from a different analysis. *See*, *e.g.*, Ex. B at 17. Presenting sensitivity and specificity scores from different analyses together is extremely misleading, given the relationship between sensitivity and specificity. Of all of Guardant's false and misleading representations, this may be the most egregious.

38. The Study also omits certain results that would contradict Guardant's marketing claims. Specifically, the Study reported a specificity score from the longitudinal analysis of 100% in patients with at least one year minimum clinical follow-up. However, the Study excluded the results from two patients whose test results would have negatively affected this specificity score. The Study excluded these patients' results because the patients had not had at least one year minimum clinical follow up; however there was no justification offered for the 1-year cutoff, especially in the context of the mis-aligned four-month cutoff described earlier and the average diagnostic lead time observed in the Study of approximately four months. Furthermore, the Study was initiated more than a year ago, and Guardant (as both a co-author of the Study and provider of testing) has had ample opportunity to follow up with the two patients well in advance of the Study's publication, issue supplemental findings, and update their marketing materials accordingly. Guardant evidently chose to ignore this additional data in its marketing claims. The plausible inference to be drawn is that Guardant has excluded unfavorable results from its marketing claims to enable its alleged specificity claim of 100%.

39. There is another issue with the Study's calculation of "longitudinal" specificity. For the "longitudinal" analysis, the Study stated that "longitudinal time points were defined by patients who had subsequent draws to the landmark timepoint." The problem is that the only patients in the Study with a blood draw subsequent to the landmark timepoint were those for whom there was a recurrence. In other words, due to the makeup of the Study cohort, the only data points in the longitudinal specificity analysis were from the affected population. Because specificity is a measure of the test's ability to correctly identify a negative result, and because there were no unaffected patients in the cohort for the test to identify, the longitudinal specificity of the test,

based on the Study data, is not 100%, but rather completely unknown. Guardant's marketing claims referencing a 100% longitudinal specificity are therefore inherently false and misleading.

40. Moreover, the Study appears to lack many of the parameters necessary to support Guardant's marketing claims. For instance, the Study appears to have evolved significantly over time, and there is no indication that there were any predefined serial blood draw schedules, or predefined endpoints. In short, the Study is missing the necessary indicia of a reliable validation, and it is misleading for Guardant to use it as the basis for its false and sweeping marketing claims.

E. ***Guardant Disseminates False and Misleading Information.***

i. Guardant Misrepresents Reveal's Performance Characteristics Compared to CEA.

41. Guardant's claims concerning the test in comparison to CEA (Carcinoembryonic Antigen) are misleading, since a non-clinically established CEA cutoff was used in the analysis. In the Study, the test was compared to CEA in the "landmark" analysis. Despite claiming in a press release that "by detecting recurrence months early than current standard of care methods like carcinoembryonic antigen (CEA)" (Ex. C), no analysis of the test's lead time as compared to CEA is presented.

42. Furthermore, the Study's definition of abnormal CEA used a non-standard cutoff of 3.4 ng/mL. The references provided in the Study do not support using this cutoff, which has, to our knowledge, not been utilized in this setting. The clinical cutoff in most widespread use is 5 ng/mL, (which is the cutoff used in prior ctDNA studies in the intended use population). Some have examined other cutoffs, but not 3.4.

ii. Guardant Misrepresents Reveal's Sensitivity Data.

43. On or around February 16, 2021, Guardant issued a press release, in which it made numerous false and misleading statements regarding the performance of its test. *See* Ex. C.

44. In the press release, Guardant claimed that its test had achieved an "industry leading" sensitivity measure of 91%. *Id.* This claim is demonstrably false. The only comparable performance data comes from the Study's "longitudinal" analysis, which reported a sensitivity measure of 69%. The test's sensitivity score of 69% is far from "industry leading"; multiple ctDNA tests on the market, including Natera's Signatera test, have achieved significantly higher sensitivity scores with longitudinal testing. Even this comparison is flawed, given that the Study's definition of "longitudinal" timepoints prevents a corresponding specificity from being calculated.

45. Guardant's claim that it achieved an "industry leading" sensitivity score of 91% is demonstrably false for two reasons: first, its test has not achieved a reliable sensitivity score of 91%, given its exclusion of 7 false negative cases in its landmark analysis; and second, its actual sensitivity score lags behind its competitors in the market, including Natera's Signatera test. This is in addition to the fact that it is inherently misleading to report sensitivity without corresponding specificity in the same patient population.

46. Guardant appears to have relied exclusively on the Study in support of its claimed 91% sensitivity rate. *See* Ex. A. As explained above, the Study reported the 91% sensitivity metric only for the scientifically invalid "surveillance analysis" and without reporting other key metrics necessary to properly make marketing claims about the test's purported sensitivity score and overall effectiveness. Therefore, the surveillance analysis cannot properly be relied upon as a measure of the test's performance.

47. In short, the Study is not sufficient for Guardant to have concluded with any reasonable degree of certainty that it actually established either a sensitivity rate of 91% for the test or "industry leading" performance.

iii. Guardant's "Industry Leading Performance" Claims Are False and Misleading.

48. Not only is Guardant's claim that its 91% sensitivity is "industry leading" false, but its more general claims of "industry leading performance" are also false. For example, its test has a pre-surgical detection rate of only 47% (Ex. A), compared to a pre-surgical detection rate of 89-94% for Natera's Signatera test. Ex. D. Guardant's test has a diagnostic lead time of approximately four months (*see* Ex. E and Ex. F, at 13) as compared to a diagnostic lead time of 8.7 months for Natera's Signatera test (*see* Ex. D). A test that lags at least one competitor by such significant margins in such important performance metrics cannot truthfully call its performance "industry leading."

49. Pre-surgical detection rate and diagnostic lead time are industry-standard metrics for the evaluation of MRD test performance. Guardant concedes the importance of pre-surgical test performance in its prior validation studies using pre-surgical samples to establish assay performance metrics, such as its claim in press releases and investor presentations of "reportable range down to 0.01 percent" (a claim unsupported by peer reviewed data). Guardant's consistent failure to report these metrics from the Study and include them in its comparative claims render those claims false and misleading.

iv. Guardant Makes False and Misleading Claims About the Analytical Performance of Reveal.

50. In its February 16, 2021 press release, Guardant claimed "the test accurately reports genomic alterations down to allele frequencies of 0.01 percent." Ex. C. There is no published peer-reviewed evidence to support this claim.

v. Guardant Cherry Picks Data.

51. Guardant made additional misrepresentations during a presentation at the January 11, 2021 JPMorgan Health Conference, which was disseminated to healthcare professionals, investors, potential patients, and others throughout the United States.

52. Recognizing the critical importance of reporting both the sensitivity and specificity rate, Guardant cherry-picked sensitivity metrics from one analysis and specificity metrics from a separate analysis. Specifically, Guardant claimed that the test had achieved a sensitivity metric of 91%—a figure derived from the Study's "*surveillance*" analysis—and a specificity metric of 100%—a figure derived from either the Study's "*longitudinal*" or "landmark" analysis, and only after excluding the two false positive cases as described above. *See* Ex. B at 17. Guardant presented these metrics together with each other, giving the clear, but false, impression that they were reported in the same analysis, when in fact they were not. Guardant intentionally misled healthcare professionals and investors into believing that they could rely upon this data to evaluate the test's effectiveness.

53. Guardant's decision to commercially promote a sensitivity metric paired with a specificity metric from a different analysis was intentionally designed to mislead the healthcare professionals, investors, and others who viewed the presentation into believing that the test was more effective than it actually is and superior to other products on the market, including Signatera. Such misinformation regarding the relative accuracy of competing oncological diagnostic products puts patients at unnecessary risk and creates waste and inefficiency in healthcare.

vi. Guardant's Claims Are Not Applicable to the Intended Use Population.

54. Guardant has made false and misleading statements regarding the test's effectiveness in other public communications.

55. In a press release posted to its website, Guardant claimed, "For oncologists, the test improves the management of ***early-stage*** CRC [colorectal cancer] patients by detecting ctDNA in blood after surgery to identify patients with residual disease who may benefit most from adjuvant therapy." Ex. G (emphasis added). However, the Study upon which Guardant relies for this claim contained at least 19% Stage-IV CRC patients who do not qualify as "early-stage" CRC patients. Guardant fails to account for the impact the significant percentage of Stage-IV patients would have on the results of the Study. Moreover, Guardant failed to identify the number of recurrences that were driven by the Stage IV group. Accordingly, Guardant's claim that the test improves the management of early-stage CRC patients is highly misleading

56. One of the authors of the Study acknowledged this limitation, stating "I think one of the limitations that we discussed in our paper was this is not a pure population of only stage II or III. It is a mix of all four stages." Molika Ashford, *Guardant MRD Test Performs Well in Small Study as Tissue-Informed Debate Takes Shape*, PRECISION ONCOLOGY NEWS (May 7, 2021), https://www.precisiononcologynews.com/liquid-biopsy/guardant-mrd-test-performs-well-small-study-tissue-informed-debate-takes-shape#.YLE36ahKj-g.

57. Guardant's claim that Reveal can "identify patients with residual disease who may benefit most from adjuvant therapy" (Ex. G) is misleading for the additional reason that there is insufficient evidence that Reveal is in fact applicable to post-surgical adjuvant treatment decisions. No performance data has been presented using plasma samples taken in the first two-to-six weeks post-surgery, which is the critical window of time for a physician to decide whether to recommend adjuvant chemotherapy.

58. Many patients in the Study received neoadjuvant therapy, which is chemotherapy and/or radiotherapy prior to surgery. Such treatment may limit eligibility for further adjuvant

treatment per established clinical guidelines. Therefore, these patients may not be considered part of the intended-use population.

F. *Guardant Disseminated Its False Claims Through Interstate Commerce.*

59. Guardant disseminated false and misleading statements regarding the effectiveness of Reveal in interstate commerce. Both the February 16, 2021 press release (Ex. C), and the undated publication discussed in Paragraphs 55 & 57, above (Ex. G) were posted on Guardant's website and transmitted throughout the world. Additionally, the false statements Guardant made during the JPMorgan Healthcare Conference (*see* Exhibit B) were made via video- and telephone conference to healthcare professionals, investors, potential patients, and other participants throughout the United States, and the presentation deck containing the misrepresentation has since been circulated to persons throughout the United States.

G. *Guardant's False and Misleading Statements Were Made in the Context of Commercial Marketing, Advertising and/or Promotion.*

60. Guardant made the false and misleading statements detailed above in the context of commercial marketing, advertising, and/or promotion. Each of the false and misleading statements recounted above were widely circulated to decision makers, including healthcare professionals, investors, and others in order to influence those decision makers to recommend, use, or otherwise choose the test over competing—and even superior—products.

H. *Guardant's False and Misleading Statements Were Material.*

61. Guardant's false and misleading statements were material. These statements misrepresented the overall effectiveness of the Reveal test—a critical consideration for any decision maker in deciding whether to prescribe, use, or otherwise choose the test over a different diagnostic product, such as Signatera. Each of the statements was intended to, and likely did influence decision makers, including healthcare professionals, investors, and others to choose the

test over other products, such as Signatera, that have been thoroughly validated, with evidence of effectiveness and performance better than Reveal.

I. *Guardant's False and Misleading Statements Have Caused and Will Continue to Cause Natera to Suffer Significant Harm.*

62. Guardant intentionally provided false and misleading information to healthcare professionals and the public in order to drive business away from its competitors, such as Natera, to purchase Guardant's Reveal test. Natera has suffered—and, absent relief from this Court, will likely continue to suffer—significant harm as a result of Guardant's false and misleading statements, including lost revenue, loss of goodwill, and diminished reputation.

COUNT I
Violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)

63. Natera incorporates by reference all allegations set forth above as if fully set forth herein.

64. Guardant made false and misleading statements, including but not limited to press releases, at least one public presentation, and written promotional materials to healthcare professionals, insurance providers, patients, and others, about the performance and quality of its Reveal tests. Guardant's false and misleading statements are designed to—and likely will continue to—mislead healthcare professionals, patients, and others into believing that the test performs better than it actually does, and that it is superior to Natera's Signatera. Guardant's statements are literally false and/or are misleading commercial speech in violation of the Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

65. Guardant made these false and misleading statements in interstate commerce, and in the context of commercial advertising or promotion as they were made for the purpose of

influencing healthcare providers, patients, and others to recommend, use, and otherwise prefer the test over competing and even superior products, such as Natera's Signatera.

66. Guardant intended for these false and misleading statements to deceive healthcare providers, patients, and others about the quality and performance of its test.

67. Guardant's false and misleading statements are material and likely will influence the decisions of healthcare providers, patients, and others.

68. Guardant's false and misleading statements are material and likely will influence healthcare providers, patients, and the general public to choose the test over Signatera.

69. Guardant made these false and misleading statements knowingly and willfully.

70. Natera has suffered—and will likely continue to suffer—significant harm as a result of Guardant's false and misleading statements, including lost revenue and loss of goodwill and diminished reputation.

71. Guardant's conduct constitutes false and misleading statements about its own goods and services and a competitor's goods and services in violation of Section 43(a) of the Lanham Act. Natera is therefore entitled to all relief available under Section 1117(a) of the Lanham Act, including but not limited to disgorgement of Guardant's profits, actual damages, and attorneys' fees and costs.

COUNT II
Common Law Unfair Competition

72. Natera incorporates by reference all allegations set forth above as if fully set forth herein.

73. Guardant made false and misleading statements, including but not limited to press releases, at least one public presentation, and written promotional materials to healthcare professionals, insurance providers, patients, and others, about the performance and quality of its

test. Guardant's false and misleading statements are designed to—and likely will continue to—mislead healthcare professionals, patients, and others into believing that the test performs better than it actually does, and that it is superior to Natera's Signatera. Guardant's statements are literally false and/or are misleading commercial speech.

74. Guardant intended for these false and misleading statements to deceive healthcare providers, insurance providers, patients, and/or others about the quality and performance of the test.

75. Guardant's false and misleading statements are material and likely will influence the decisions of healthcare providers, patients, and others.

76. Guardant's false and misleading statements are material and likely will influence healthcare providers, patients, and the general public to choose the test over Signatera.

77. Guardant made these false and misleading statements knowingly and willfully.

78. Natera has suffered—and will likely continue to suffer—significant harm as a result of Guardant's false and misleading statements, including lost revenue and loss of goodwill and diminished reputation.

79. Guardant's conduct constitutes false and misleading statements about its own goods and services and a competitor's goods and services. Natera is entitled to all appropriate relief at law or in equity.

PRAYER FOR RELIEF

WHEREFORE, Natera respectfully asks this Court to award the following relief:

1. Judgment in favor of Natera and against Guardant;

2. An Order permanently enjoining Guardant from disseminating or causing the dissemination of false and misleading statements regarding its products or Natera's products;

3. An Order requiring Guardant to publish corrective statements;

4. Natera's actual monetary damages, including but not limited to Natera's lost business and profits, harm to Natera's goodwill and reputation, as well as Guardant's ill-gotten and unjustly derived gains;

5. Punitive and exemplary damages;

6. Pre- and post-judgment interest on all damages awarded, as permitted by law;

7. Costs associated with this litigation, including expert witness fees, as permitted by law;

8. Attorneys' fees to the extent permitted by law;

9. Statutory damages as permitted by law;

10. Such other relief at law or in equity to which Natera is entitled.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Natera demands a trial by jury on all issues so triable.

Date: May 28, 2021

Respectfully submitted,

WINSTON & STRAWN LLP

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